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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,217	06/05/2000	EMMANUELLE GUILLOT	1029/00196	1395

7590

02/27/2002

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,217

Applicant(s)

Guillot et al

Examiner

Jehanne Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 6, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Currently, claims 1-30 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 103

3. Claims 1-23 and newly added claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Manz et al (Water Research, vol. 28, pp 1715-1723, 1994), Wagner et al (Systematic and Applied Microbiology, vol. 18, pp 251-264; 1995) and De Los Reyes et al (Applied and Environmental Microbiology, vol. 63, pp 1107-1117; 1997) in view of Mobarry et al (Applied and Environmental Microbiology, June 1996, vol. 62, pp 2156-2162).

Manz teaches the in situ characterization of microbial organisms in waste water treatment plants (see abstract). Manz teaches that rRNA probes can be used to identify bacteria using in situ hybridization (see p. 1715, col.2). Manz teaches extracting and harvesting cells from sewage

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plants (p. 1716, col 2). Manz teaches using both species specific and universal fluorescent rRNA probes (p. 1717, col 1) for in situ hybridization. Manz teaches that cells were fixed prior to in situ hybridization with mixtures of paraformaldehyde and ethanol depending on the type of cell wall structure (gram positive vs. Gram negative bacteria, see p 1717, col. 2). Manz teaches that after hybridization nucleic acid was extracted from cells and that nucleic acid concentrations were determined, followed by immobilization of nucleic acids on nylon membranes and probing with digoxigenin-labeled oligonucleotides.

Wagner teaches in situ identification of ammonia oxidizing bacteria (see abstract). Wagner teaches that 16S rRNA oligonucleotides can be used to detect microbial species. Wagner teaches fixing cells, hybridization using species specific and universal bacterial probes in formamide, washing at 48 deg. C. In a buffer containing NaCl, Tris/HCL, and SDS. and the quantification of probe conferred fluorescence (pp 252-253).

De Los Reyes teaches group specific rRNA hybridization probes to characterize filamentous foaming in activated sludge systems (see abstract). De Los Reyes teaches using fluorescence tagged group specific as well as universal probes S-Univ-1390 and Bact-0338 (see p. 1108, col 1) in an in situ hybridization method to detect and quantify bacteria (see pp 1108). Mobarry et al teach phylogenetic probes for analyzing nitrifying bacteria in methods of in situ hybridization (see abstract). Mobarry teaches using probes Nb 1000 and Nso 1225. Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to develop a method of identifying and quantifying bacterial populations in samples

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for the purpose of diagnosing infectious disease or monitoring contamination for treatment of sludge and wastewater or sewage systems as the state of the art was very high with regard to such at the time the invention was made. As exemplified above, the ordinary artisan would have been taught the following: 1) bacterial populations could be identified and quantitated using in situ hybridization and 2) such methods were carried out using both species specific as well as universal probes (it is noted that in a method of detecting proteobacteria, the ordinary artisan would have been taught the use of specific probes Nso 1225 and Nb 1000, and the use of universal probes S-Univ-1390 and Bact-0338). The claims as written encompass extraction of DNA from cells followed by fluorescence detection of bound probes outside cells which is taught by Manz.

Response to Arguments

The response states that claim 1 was amended to better define the extraction and separation of the hybridized probes from the cells for quantitative detection. This statement as well as the amendments to claims have been thoroughly reviewed but were not found persuasive as the amendment to claim 1 still does not make clear that the probes were separated from targets and eluted without cell lysis or extraction of DNA from cells. The claims as written still encompass extraction of DNA from cells followed by fluorescence detection of bound probes outside cells which is taught by Manz. Claim 14 recites extraction using a denaturing agent and at a temperature higher than the melting temperature of the specific probe under consideration,

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however such methods are well known in the art for separating bound probe:target complexes. The claim does not recite specific conditions or positive process steps such that the claims make clear that only the hybridized probes are being eluted without target DNA *from whole cells* or that cell lysis has not occurred.

New Grounds of Claim Objections

4. Claim 5 is objected to because of the following informalities: Claim 5 should read "A method...". Claim 7 is objected to because it appears that the phrase "followed by" should read "following" such that claim 9 follows logically after claim 7. If this is not the case, then it is not clear how in claim 9 dehydration follows fixation, both before the contacting step, but in claim 7, the contacting step is performed *before* fixation. In other words, it is unclear how claim 9 further limits claim 7. Appropriate correction is required.
5. No claims are allowable.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

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Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jehanne Souaya
Patent examiner
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Feb. 15, 2002



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600